Visit at Integer facility on use of TCE in vapor degreasing in the manufacture of medical devices

Biweekly Summary

On October 19, 2017, CCD, CESSD, and RAD staff visited Integer's facility in Minneapolis, MN. Integer was formed from the merger of Greatbatch, Lake Region Medical, and Electrochem, and specializes in the design and development of medical devices and power solutions for the medical and non-medical markets. EPA toured Integer's facility where they make various medical devices, for a demonstration of open-top vapor degreasing, spray degreasing, enclosed vapor degreasing, and aqueous degreasing. Integer also provided a tour of their manufacturing process of medical devices and showed samples of their actual medical products. Additionally, they discussed the research and testing they've done on non-TCE alternatives and argued that there are no effective alternatives available that can clean all of the medical devices they produce and are compatible with lubricants they use. Validation by FDA of new cleaning process in medical device manufacturing process, which typically takes about 3 years, was also highlighted as a major challenge to transitioning to TCE alternatives

Additional Information

- The meeting was arranged by David Crandell of Parts Cleaning Technologies who is a consultant to Integer. David participated in the TCE Small Business Advocacy Review (SBAR) Panel and has actively followed the TCE rulemaking under TSCA together with the Halogenated Solvents Industry Alliance (HSIA).

- Participants:
    - Toni Krasnic (CCD), Nhan Nguyen (RAD), Yadi Lopez (RAD), Lynne Blake-Hedges (CESSD), EPA.
    - Kurt Carlson and other senior managers, Integer (we're still waiting for the full list of attendees).
    - David Crandell, Parts Cleaning Technologies.

- There were a number of follow-up items for Integer from the meeting that EPA has yet to receive:
    - List of Integer participants (in-person and on-line)
    - Copy of Integer's non-CBI presentation
    - Any exposure data at Integer
    - Sample FDA approval application
    - Sample customer specification
    - Any data on solvent testing done by Integer

- Key issues raised by Integer during the site visit:
    - Integer's precision tubing manufacturing process for medical devices (namely, the combination of hard metals with complex geometries and use of various lubricants for medical applications) requires use of TCE. No other options researched by Integer have been feasible at this time.
        - EPA has requested additional information on the research Integer has done on alternative chemicals and processes.
    - Any change to the manufacturing process requires re-validation testing to ensure that existing quality standards and customer specifications are met. In many cases subsequent regulatory approval by the Food and Drug Administration (FDA) or other international

equivalents are also required. Regulatory revalidations are expensive and approval timelines are long and vary based on the customer and class of medical device.
        - EPA has requested additional information on the customer specifications and FDA approval process.
    - Integer has also evaluated aqueous based cleaners. They determined that aqueous cleaners will not effectively remove most of the materials in Integer's extreme pressure lubrication system. New lubricants and coating systems would need to be developed that are compatible with the aqueous cleaners. Integer has not evaluated the use of any Type V vapor degreasing systems.
        - EPA has requested additional information on the research Integer has done on aqueous degreasing.
    - If the TCE ban rule is finalized, Integer requested that the compliance period be increased to at least 5 years.

- Integer's exposure monitoring showed exposures at 10 to 50 ppm as an 8-hour Time Weighted Average.
    - EPA requested additional information on exposure data.

- Additional comments from Integer are available in their comments submitted during the public comment period of TCE rulemaking: EPA-HQ-OPPT-2016-0387-0688.